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Date of Signature and Deposit: July 17, 1996



A handwritten signature in black ink, appearing to read "Nicholas J. Seay".

PATENT

7/16/96

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Thompson

08/376,327

Filed: January 20, 1995

Title: PRIMATE EMBRYONIC STEM CELLS

Group Art Unit: 1808

Examiner: Dadio

Attorney Docket No.: 960296.92905

Dated: July 17, 1996

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PETITION AND FEE FOR EXTENSION OF TIME (37 CFR 1.136(a))

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant hereby petitions the Assistant Commissioner for Patents to extend the time for response to the Office Action dated 01/17/96 for three(3) month(s) from 04/17/96 to 07/17/96.

Applicant is

a small entity, the verified statement for which:

is attached.

was filed previously.

other than a small entity.

Extension:	Fee for Non-small Entity	Fee for Small Entity	
<input type="checkbox"/> one month	\$110.00	\$55.00	
<input type="checkbox"/> two months	\$380.00	\$190.00	
<input checked="" type="checkbox"/> three months	\$900.00	\$450.00	
<input type="checkbox"/> four months	\$1,400.00	\$700.00	Fee <u>\$450.00</u>

Please charge the above-identified fee to Deposit Account No. 17-0055. Any additional fee due in this application and any overpayment should be charged or credited to Deposit Account No. 17-0055. A duplicate copy of this paper is enclosed.

A response to the Office Action

is filed herewith.

has been filed.

Respectfully submitted,

By:

Nicholas J. Seay, Reg. No. 27,386

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Claims 1-11 are currently pending in the instant application and have been examined on the merits. Claims 1-8 appear to be drawn to a purified preparation of primate embryonic stem cells wherein stem cells have certain morphological characteristics. Claims 9-10 appear to be drawn to a method of isolating primate embryonic stem cells. The method comprises isolating the blastocyst, isolating cells from the ICM, plating the ICM cells on an embryonic fibroblasts, dissociating the ICM derived cells, replating the ICM derived cells on an embryonic feeder layer, selecting the embryonic cells and culturing the selected cells. Claim 11 is drawn to a primate embryonic stem cell line isolated by the claimed method.

The rejections under 35 USC 112 second paragraph have been overcome by applicant's amendment.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-8 and 11 remain rejected under 35 U.S.C. § 103 as obvious over Nation/World

(Nov. 4, 1994).

twj

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Applicant should submitt a 37 CFR § 1.131 declaration to ~~provide the~~ properly antedate the reference.

Nation/World discloses isolated embryonic stem cells from rhesus monkeys and marmosets. Nation/World indicates that these cells are the parent cells of the many tissues in the primates body, and can be induced to grow into any kind of tissue.

Nation/World does not specifically mention the specific morphological characteristics which are indicated in the claims, however, these characteristics are inherent features of the particular type of cell--rhesus monkey embryonic stem cells. Furthermore, the method of obtaining the cell line does not appear to patentably distinguish the embryonic stem cells from the prior art.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' isolated embryonic stem cells differ and, if so, to what extent, from the cells discussed in the references. Accordingly, in as much as the examiner has established that the prior art cells, which are obtained from the same source, rhesus monkeys, as that claimed, likewise shares the property of being able to be induced to grow into any kind of tissue, she has reasonably demonstrated a reasonable likelihood/possibility that the compared cells are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to applicants.

Accordingly, the claimed invention would have been at least *prima facie* obvious, if not anticipated, by one of ordinary skill in the art at the time the claimed invention was made, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Claims 9-11 are rejected under 35 U.S.C. § 103 as being unpatentable over Piedrahata et al. (Theriogenology).

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Applicant has alleged that the basis of the examiner's rejection is "obvious to try" however this is not found to be persuasive. The examiner contends that the method of Piedrahata is identical to the claimed process with the exception of the source of the cells. The reference has applied the method to murine, porcine & ovine animals, three diverse categories of mammals and therefore the method could be applied to other mammals such as primates with a reasonable expectation of success.

The claims are drawn to a method of isolating primate ES cells. ICM cells are isolated from the blastocyst, the ICM cells are then plated on embryonic fibroblast feeder layers, dissociated, replated onto embryonic feeder layers and the selected. The selected ES cells are then maintained on a fibroblast feeder layer.

Piedrahata et al. teach a method of isolating murine, porcine and ovine embryonic stem cells. The blastocysts were isolated and then the cells from the ICM were isolated. These ICM cells were plated on embryonic fibroblast feeder layers (STO feeder layers). After plating the growing ICM cells were dissociated and replated onto fresh feeder layers. ES cells were then

selected based on a large nucleus and prominent nucleoli. These selected cells were then cultured on fresh feeder layer in order to prevent differentiation.

The only apparent difference between the method of Piedrahata et al. and that of the instant claims is that the claims isolate primate ES cells whereas Piedrahata et al. isolates murine, porcine and ovine ES cells. However, one of ordinary skill in the art would have a reasonable expectation of success in isolating primate ES using the same method as taught by Piedrahata et al for isolating murine, porcine or ovine ES cells.

As decided in In re O'Farrel, 7 USPQ 2d 1673 (Fed. Cir. 1988), obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. In re Merck & Co., 800 F.2d at 1098, 231 USPQ at 380; Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1461, 221 USPQ 481, 488 (Fed. Cir. 1984); In re Papesch, 315 F.2d 381, 386-387, 137 USPQ 43, 47-48 (CCPA 1963). For obviousness under 35 U.S.C. 103, all that is required is a reasonable expectation of success. In re Longi, 759 F.2d 887, 897, 225 USPQ 645, 651-652 (Fed. Cir. 1985); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).

Accordingly, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, especially in the absence of sufficient, clear and convincing evidence to the contrary.

I. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kristin K. Larson whose telephone number is (703) 305-7811.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

KL
Kristin K. Larson
October 28, 1996

M. G. Wityshyn
MICHAEL G. WITYSHYN
SUPERVISORY PATENT EXAMINER
GROUP 1800

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